Applicants: P. Bonutti et al. Application No.: 10/779,978

Examiner: M. Mashack

REMARKS

Claims 24, 35-37, 44, and 59 have been amended. Claims 62 and 63 have been added. Claims 25, 43, 48, 54, 56, and 58 have been cancelled. Claims 1, 6, 9, 11-13, 15-23, 26-34, 40-42, 47, and 49-51 were cancelled in a previous Response(s). Accordingly, claims 2-5, 7, 8, 10, 14, 24, 35-39, 44-46, 52, 53, 55, 57, and 59-63 are presented for the Examiner's review and consideration. Applicants believe the claim amendments, cancellations, and additions and the accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

Rejections under 35 U.S.C. §112, First Paragraph

The rejection with respect to claim 25 is now moot as claim 25 has been canceled, without prejudice and without conceding the validity of the rejection. Applicants respectfully request reconsideration of the rejection of claim 37 in light of the amendment to this claim. Finally, Applicants respectfully request reconsideration of the rejection of claims 59-61 in light of the amendment to claim 59.

Rejections under 35 U.S.C. §102(b)

Claims 2, 4, 5, 7, 8, 10, 14, 24, 35-38, 44-46, and 59-61 were rejected under 35 USC §102(b) as allegedly being anticipated by Yoon (U.S. Patent 5,908,429; hereinafter "Yoon"). For reasons set forth below, Applicants respectfully submit that these rejections should be withdrawn.

Yoon has been discussed in previous Responses and these discussions are incorporated herein by reference. Independent claims 24, 35, and 59 recite similar recitations and will be addressed together.

Applicants: P. Bonutti et al. Application No.: 10/779,978 Examiner: M. Mashack

Claim 24 is directed to a surgical device for securing tissue and comprises a first member including a first compression element; a tubular second member including a proximal end and a distal end; an energy source operably connected to the first compression element; and an elongated insulation sleeve controllably positionable over the tubular second member. The tubular second member is movable along a linear path relative to the first member from a first position to a second position, and the first compression element is configured to contact a retainer. The insulation sleeve insulates suture from energy from the energy source and the elongated insulation sleeve moves independently of movement of the tubular member.

Claim 35 also is directed to a surgical device for securing tissue and comprises a first member including a first compression element; a tubular member configured to receive a retainer therein; an energy source operably connected to the first compression element to deliver energy to the gapped portion of the tubular member; and an elongated insulation sleeve controllably positionable over the tubular member. The tubular member is slidably positionable over the first member, such that the first compression element is in opposing relation to the second compression element. The elongated insulation sleeve is controllably slidable from a first sleeve position, covering the gapped portion of the tubular member, to a second sleeve position, uncovering the gapped portion of the tubular member. The sliding of the insulation sleeve is independent of movement of the tubular member. The device also includes a safety switch operably connected to the elongated insulation sleeve. The safety switch has an off position operable to prevent delivery of energy to the gapped portion of the tubular member when the elongated insulation sleeve is in the second sleeve position. The safety switch moves to the off position with movement of the elongated insulation sleeve to the second sleeve position.

Claim 59 is also directed to a surgical device for securing tissue. The device comprises first and second members, the second member movable with the respect to the first member from a first position to a second position, the first member configured to contact a retainer in the second position; an elongated insulation sleeve movable with respect to both the first and second members, movement of the elongated insulation sleeve independent of movement of the second member; and an energy source operably connected to the first member, the energy source

Applicants: P. Bonutti et al. Application No.: 10/779,978 Examiner: M. Mashack

operable for application of energy to the retainer. The elongated insulation sleeve is further positionable to limit the application of energy from the energy source.

Applicants respectfully submit that Yoon does not teach all the elements as recited in independent claims 24, 35, and 59. For example, each of these claims recite that the insulation sleeves moves independent of movement of the tubular member. In the Office Action, element 512 of Yoon is identified as the "insulation sleeve" and element 536 of Yoon is identified as the "second tubular member." There is nothing in Yoon that states that element 512, which Yoon identifies as a barrel, moves with respect to element 536, which Yoon simply identifies as an outer member. If anything, barrel 512 is stationary and outer member 536 moves.

Independent claim 35 also recites a safety switch operably connected to the elongated insulation sleeve. The safety switch has an off position operable to prevent delivery of energy to the gapped portion of the tubular member when the elongated insulation sleeve is in the second sleeve position. The safety switch moves to the off position with movement of the elongated insulation sleeve to the second sleeve position. Although the Office Action asserts that an on/off switch is inherent and can be a "safety switch", there is nothing in Yoon, inherent or otherwise, that teaches or suggests that anything that even arguably could be considered as a safety switch "moves to the off position with movement of the elongated insulation sleeve to the second sleeve position" as recited in claim 35.

Independent claim 44 is also novel with respect to Yoon. This claim, like the other independent claims, is directed to a surgical device for securing tissue that comprises a first member including a first compression element; a tubular member including a gapped portion configured to receive a retainer therein, the gapped portion including an integrated second compression element; an energy source operably connected to the first compression element; and an elongated insulation sleeve controllably positionable over the tubular member from a first sleeve position to a second sleeve position. The tubular member is slidably positionable over the first member such that the first compression element is in opposing relation to the second compression element. The elongated insulation sleeve is further positionable to insulate the suture from application of energy from the energy source. The elongated sleeve further

Applicants: P. Bonutti et al. Application No.: 10/779,978

Examiner: M. Mashack

comprises a collar member configured to receive an end portion of a suture, with the collar including means for maintaining tension in the suture.

Applicants respectfully submit that Yoon does not teach all the elements as recited in independent claim 44. For example, there is nothing on Yoon that serves both to insulate the suture from the application of energy and maintain tension in the suture. Barrel 512, even if it can be viewed as the insulation sleeve, and collar 22, even if this can be viewed as the recited collar member, do not have any means for maintaining tension in the suture.

Accordingly, based upon all of the above, Applicants submit that independent claims 24, 35, 44, and 59 are patentable over Yoon. As claims 2, 4, 5, 7, 8, 10, 14, 60, and depend from claim 59; claim 57 depends from claim 44; claims 36-39, 45, 46, and 55 depend from claim 35; and claim 53 depends from claim 24, these dependent claims necessarily include all the elements of their respective base claims. Thus, Applicants respectfully submit that these dependent claims are allowable over Yoon at least for the same reasons.

In light of all of the foregoing arguments, Applicants respectfully request reconsideration and withdrawal of the rejections of claims under 35 U.S.C. §102(b).

Rejections under 35 U.S.C. §103(a)

Claims 3, 39, and 48 were rejected under 35 USC §103(a) as allegedly being unpatentable over Yoon. Claims 25 and 43 were rejected under 35 U.S.C. §103(a) as being unpatentable over Yoon in view of Vancaillie. (U.S. Patent 5,980,520; hereinafter "Vancaillie"). Claims 52, 53, 55, 57, and 58 were rejected under 35 U.S.C. §103(a) as being unpatentable over Yoon in view of James S. Bates et al. (U.S. Patent 6,348,056 B1; hereinafter "Bates"). Claims 54 and 56 were rejected under 35 USC §103(a) as allegedly being unpatentable over Yoon in view of Vancaillie and further in view of Bates.

For reasons set forth below, Applicants respectfully submit that these rejections should be withdrawn.

Applicants: P. Bonutti et al. Application No.: 10/779,978

Examiner: M. Mashack

It is noted that the references are described individually only to clarify what each reference teaches. Thus, the separate description of references presented herein is not and should not be interpreted as an attempt at arguing each reference separately.

As an initial matter, Applicants notes that claims 25, 43, 48, 54, 56, and 58 have been cancelled without prejudice and without conceding the validity of the rejections.

Like Yoon, Bates has been discussed in previous Responses and these discussions are incorporated herein by reference. Vancaillie discloses a desiccation electrode and is cited solely to assert that it was commonly known in the art at the time of the invention to bias an energy transmitting member into a protective sheath. Applicants respectfully submit that neither Bates nor Vancaillie, either alone or in combination, remedies the deficiencies of Yoon with respect to independent claims 24, 35, 44, and 59 as discussed above. As claims 3 and 52 depend from claim 59; claim 57 depends from claim 44; claims 39 and 55 depend from claim 35; and claim 53 depends from claim 24, Applicants respectfully submit that these dependent claims are patentable over the cited references at least for the same reasons as their respective independent claims.

In light of all of the foregoing arguments, Applicants respectfully request reconsideration and withdrawal of the rejections of claims under 35 U.S.C. §103(a).

Conclusion

In light of the foregoing amendments and remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this Response or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

Applicants: P. Bonutti et al. Application No.: 10/779,978

Examiner: M. Mashack

The fee for a three month extension of time is believed to be due and are being paid via credit card. No other fees are believed to be due at this time. However, please charge any other required fee (or credit overpayments) to the Deposit Account of the undersigned, Account No. 503410 (Docket No. 782-A03-024).

Respectfully submitted,

/Paul D. Bianco/

Paul D. Bianco, Reg. # 43,500 Customer Number: 33771 FLEIT GIBBONS GUTMAN BONGINI & BIANCO P.L. 21355 East Dixie Highway, Suite 115 Miami, Florida 33180

Tel: 305-830-2600; Fax: 305-830-2605

e-mail: pbianco@fggbb.com